FEB 2 8 2014

LERADO GLOBAL (MACAO COMMERCIAL OFFSHORE) LIMITED
Avenida Marciano Baotista, No.26-54b, 7 Andar, H7 Edif. Centro Com. Chong Fok Macau, China
TEL: 852-5-2475605 FAX: 852-5-2379627

K130982

" 510(k) SUMMARY "

Date summary prepared: December 31, 2013

Submitter's Name: LERADO Global (MACAO Commercial Offshore) Limited
Avenida Marciano Baotista, No.26-54b, 7 Andar, H7 Edif. Centro Com., Chong Fok Macau, China.

Name of Contact Person: Dr. Jen, Ke-Min
Tel: +852-5-2475605 Fax:+852-5-2379627
Email:ceirs.jen@msa.hinet.net

Device Name:

Proprietary Name: LERADO Power Wheelchair, DF4110
Common or Usual Name: Powered Wheelchair
Classification Name: Powered Wheelchair, Class II,
21 CFR 890.3860

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

LERADO, Powered Wheelchair, DF4110 series include the devices with the same mechanic and electric controlling structure but with different colors of body and veneer. The LERADO Powered Wheelchair, DF4110 is an indoor / outdoor wheelchair that has a base with four-wheeled with a seat and is battery operated. The device can be disassembled for transportation, easily foldable and is provided with an off-board battery charger. The movement of the wheelchair is controlled by the rider who uses hand controls located at the top of the steering column.

Performance Testing:

- ANSI / RESNA WC Vol.2 Wheelchair Part 2: Electromagnetic compatibility, 2009.
- ISO7176-1 Wheelchairs - Part 1: Determination of Static Stability, 1999.
- ISO7176-2 Wheelchairs - Part 2:Determination of dynamic of electric wheelchairs, 2001.
- ISO7176-3 Wheelchairs - Part 3: Determination of effectiveness of brakes, 2003.

- ISO7176-4 Wheelchairs - Part 4:Determination of energy consumption of electric wheelchairs, 2008.
- ISO7176-5 Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space, 2008.
- ISO7176-6 Wheelchairs - Part 6:Determination of maximum speed, acceleration and retardation of electric wheelchairs, 2001.
- ISO7176-7 Wheelchairs - Part 7: Measurement of seating and wheel dimensions, 1998.
- ISO7176-8 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths, 1998.
- ISO 7176-9 Wheelchairs - Part 9: Climatic tests for electric wheelchairs, 2009.
- ISO7176-10 Wheelchairs - Part 10:Determination of the climbing ability of electric wheelchairs, 2008.
- ISO7176-11 Wheelchairs - Part 11: Test dummies, 1992.
- ISO7176-13 Wheelchairs - Part 13:Determination of coefficient of friction of test surfaces, 1989.
- ISO7176-15 Wheelchairs - Part 15:Requirements for information disclosure, documentation and labelling, 1996.

Materials of the subject device:

Components	Materials	Test regulation
FRAME	High-Quality SPCC Steel Pipe	CAS# 7439-89-6
SEAT Leather	PVC Leather	EN 1021-1/-2:2006 Resistant to ignition source smouldering cigarette, and match flame equivalent
UPHOLSTERY FABRIC & LINING	Fabric and Foam	ANSI/BIFMA X5.1-1993, ISO 8191-1/-2, ISO 7176-16: resistance to ignition
TIRE	PU Solid Tire	CAS# 101-68-8

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Specifications of the subject device:

- Frame Material：High Quality SPCC Steel Pipe
- Framework： Unfoldable
- Controller: Dynamic Shark 40A
- Motor output：
- Motor:

  Trade name: Chiapua Components Group

  Type: GD35D-05T, DC24V Direct Current Carbon Brush Motor

  Size: ⌀88.5mm x 109mm

  Output： 200W

  RPM: 2955RPM
- Battery： 35Ahx12Vx2pcs
- Charger：3A
- Brake： Electromagnetic brake
- Max Speed： 6km/h (4mile/h)
- Continuous trip distance：20km /12.4mile
- Climbing ability：6°
- Front wheel： 10" PU Solid tire
- Rear wheel： 6" PU Solid tire
- Seat depth： 410 mm (16.1")
- Seat height： 530 mm (20.9")
- Seat width： 475 mm (18.7")
- Max loading：136kgs(300lbs)
- Available color： black (body), red/yellow/blue (veneer)
- Total weight：70.3 kgs / 155 lbs
- Ground clearance：48 mm / 1.9"
- Turning diameter：1,230 mm / 48.4"
- Dimension (L*W*H): 1,040 * 625 * 1,250 mm

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Comparison table

ITEMS	PREDICATE DEVICE	SUBJECT DEVICE
BRAND NAME	*LERADO*	LERADO
MANUFACTURER	*LERADO GROUP*	LERADO GROUP
MODEL NO	*PB Series*	DF4110 Series
510K NO	*K070433*	K130982
INTENDED USE	*The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.*	SAME
Frame	*Fixed (unfordable)*	SAME
Overall dimension **Overall length** **Overall width**	 *650 mm / 25.59"* *600 mm / 23.62"*	 1,040 mm / 40.94" 625 mm / 24.60"
Weight limit	*136 kgs / 300 lbs*	SAME
Maximum speed	*6.0 km/hr (4mile/h)*	SAME
Electronics controller	*Dynamic, DA50*	Dynamic, Shark 40A
Batteries **Quantity Type** **Range per charge**	 *Two* *36Ah 12VDC* *36 km / 22.5 miles*	 *Two* *35Ah 12VDC* *20 km / 12.4 miles*
Suspension	*Cross brace*	SAME
Rear wheels	*10" solid x 2"*	6" PU solid tire
Casters	*8" solid x 2"*	10" PU solid tire

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ITEMS	PREDICATE DEVICE	SUBJECT DEVICE
Footplates	*ABS*	SAME
Frame material	High-Quality SPCC Steel Pipe	SAME
Motor		
Trade name	Motion Technology Electric & Machinery Co., ltd.	Chiapua Components Group
Model number	EC82M	GD35D-05T
power	320W	200W
Type	24VDC Carbon-brush	24VDC Carbon-brush
Diameter	ϕ82mm *149mm	ϕ88.5mm * 109mm
Speed	4600 RPM	2955 RPM
Seat size		
Width	46~61 cm / 18~24"	47.5 cm / 18.70"
Depth	46 cm / 18"	41 cm / 16.14"
Height	53~58 cm / 21~23"	53 cm / 20.86"
Incline	*6 degrees*	6 degrees
Back upholstery	*Fabric*	SAME
Armrest types	*Flip-backward*	SAME
Wheelchair Weight w/batteries	**87 kgs**	**70.3 kgs**
Charger		
Model	HIGH POWER HP8204B	HIGH POWER HP1211B1
Voltage	24VDC	24VDC
Output current	5A	3A

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ITEMS	PREDICATE DEVICE	SUBJECT DEVICE
Wheel Lock	*Push-to-Lock*	SAME
Type of brake	*Dynamic electromagnetic brake*	SAME
Warranty	***3 years**: Main frame* ***1 years**: Controller / gear motor / batteries w/o exhaustive and wear parts*	SAME

Substantial equivalence comparison discussion:

We know from the above table that the intended use between two devices is the same; and they are from the same LERADO group and the same manufacturer. Mainframes of two devices are not foldable and all meet the strength and fatigue tests, thus they are similar for the material aspects. The overall dimensions are similar. The weight capabilities, maximum speed, suspension of cross brace, footplates, armrest, and the warranty are all the same. Back upholstery material is also the same fabric.

Especially, the electronic systems of two devices, for instance the motor, batteries, and charger are from the same supplier, and both are UL-certified. For the electronic controller, the predicate device uses the Dynamic DA series and the subject device use Dynamic Shark series, and both are UL-certified. Thus the same safety level for the two devices is assured.

Incline capabilities for the two devices are the same. The subject device and the predicate device can both drive under 6 degrees of incline. We place the limit of 6 degrees of climbing incline on the page 2 of the Owner's Manual and the user is not allowed to operate the device on the incline over the specified angle. The safety levels of the two devices are the same when operating the devices on the adequate inclines. They are substantially equivalent.

The cruising ranges per charge are different; and the subject device is 12.4 miles and 22.5 miles for the predicate device. Certainly the real range depends on the practical environmental conditions, i.e., loading weight, driving surface, incline angle, and temperature. For the real life use, the two devices are substantially equivalent.

To sum up, **the major differences existing between the two devices are the overall dimensions and cruising ranges.** The overall appearance differences are not safety aspect. Thus the new device is substantially equivalent to the predicate devices in this aspect.

Based on the above the information and the analysis, we know that the subject device and the predicate device have the same intended use, the same technological aspects and only minor dimensions and material differences exist. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

Lerado Global Limited
c/o Dr. Jen, Ke-Min
Avenida Marciano Baotista, No. 26-54b, 7 Andar
H7 Edif Centro Com. Chong Fok Macau
CHINA

Re: K130982
Trade/Device Name: LERADO Power Wheelchair, Model DF4110
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 17, 2014
Received: January 30, 2014

Dear Dr. Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130982

Device Name
LERADO Power Wheelchair, model DF4110

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."